

Award Number: W81XWH-11-2-0169

TITLE: Negative Gauge Pressure Moisture Management and Secure Adherence
Device for Prosthetic Limbs

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REPORT DATE: March 2013

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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| REPORT DOCUMENTATION PAGE | | | | Form Approved OMB No. 0704-0188 | |
|---|-------------|-------------------------|----------------------------|---|---|
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| 1. REPORT DATE March 2013 | | 2. REPORT TYPE Final | | 3. DATES COVERED 18-July-2011 - 17-February-2013 | |
| 4. TITLE AND SUBTITLE Negative Gauge Pressure Moisture management and Secure Adherence Device for Prosthetic Limbs | | | | 5a. CONTRACT NUMBER | |
| | | | | 5b. GRANT NUMBER W81XWH-11-2-0169 | |
| | | | | 5c. PROGRAM ELEMENT NUMBER | |
| 6. AUTHOR(S) Glenn K. Klute, PhD E-Mail: gklute@u.washington.edu | | | | 5d. PROJECT NUMBER | |
| | | | | 5e. TASK NUMBER | |
| | | | | 5f. WORK UNIT NUMBER | |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Seattle Institute for Biomedical and Clinical Research Seattle, WA 98108 | | | | 8. PERFORMING ORGANIZATION REPORT NUMBER | |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 | | | | 10. SPONSOR/MONITOR'S ACRONYM(S) | |
| | | | | 11. SPONSOR/MONITOR'S REPORT NUMBER(S) | |
| 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited | | | | | |
| 13. SUPPLEMENTARY NOTES | | | | | |
| 14. ABSTRACT The overall objective of this research was to develop and test a novel prosthesis incorporating a negative gauge pressure moisture management and secure adherence device. This novel Dynamic Air Exchange (DAE) prosthesis is intended for active lower limb amputees who work and perspire in demanding environments. The results show the DAE prosthesis was able to expel a significant amount of perspiration during a 30-minute treadmill walk at self-selected speed. Approximately 1 g of sweat was removed from the prosthesis during the protocol. The DAE prosthesis exhibited approximately 4 mm more residual limb "pistoning" than a Suction prosthesis (current standard-of-care), the difference was not thought to be clinically meaningful. No effect was found on residual limb skin temperatures. For both the DAE and Suction prostheses, the residual limb skin temperature generally stayed constant during an initial 30-minute rest period, increased substantially (~3 °C) during a 30-minute walk at self-selected speed, and fell gradually (~1 °C) during a second 30-minute rest period. Importantly, the DAE prosthesis was subjectively acceptable to the participants as they reported a positive experience. | | | | | |
| 15. SUBJECT TERMS Lower extremity amputee, transtibial amputation, artificial limb, prosthesis, skin temperature, perspiration | | | | | |
| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | | USAMRMC |
| U | U | U | UU | 46 | 19b. TELEPHONE NUMBER (include area code) |

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I. INTRODUCTION

The overall objective of this research is to evaluate and refine a novel prosthesis incorporating a negative gauge pressure moisture management and secure adherence device (see Figure 1). This novel prosthesis is intended to improve the limb adherence and expel perspiration from the prosthesis of active lower limb amputees who work and perspire in demanding environments. The work of this project includes developing and fabricating several of these novel prostheses and conducting tests to reveal how well it can provide secure adherence and remove perspiration compared to the current standard-of-care (i.e., total surface bearing suction socket).

The original statement of work stipulated a one year period of work beginning on July 18, 2011 and ending on July 17, 2012. An important revision was the approval of a no-cost extension to revise the completion date from July 17, 2012 to March 17, 2013.

The scope of activities to be performed, under contract number W81XWH-11-2-0169, includes the following tasks:

1. Develop the novel prosthetic airflow control system,
2. Develop the test prostheses, and
3. Conduct human subject experiments.



Figure 1: Assembled test prosthesis worn by a transtibial amputee.

II. BODY

The research accomplishments for the three “scope of activity” tasks will be identified and discussed in context of the approved Statement of Work (SOW) and related milestones for the period of work beginning on July 18, 2011 and ending on March 17, 2013. The complete d

SOW Summary

This purpose of this project was to develop a novel prosthetic system incorporating a negative gauge pressure moisture management and secure adherence device for lower limb amputees. A human subject experiment with transtibial amputees was performed to compare the performance of the novel prosthesis with the current standard-of-care (i.e., a total surface bearing suction socket). The results have been documented and are being disseminated to program officials, clinicians, and amputees.

Brief Description of Novel Prosthesis

A novel prosthesis design, described as a negative gauge pressure moisture management and secure adherence device for the artificial limb, employs regulated negative gauge pressure to facilitate moisture management (perspiration removal) for the amputee's lower residual limb. The system creates and maintains a negative pressure differential between the residual limb and the prosthetic liner with the aid of a small, low power pump attached to the prosthetic limb which operates on demand. The pressure differential draws fresh air from outside the limb which flows along the skin surface (facilitating moisture removal) to a distal collection port (see Figure 2). The now moisture-laden air, and perspiration if the activity level is high enough, is then expelled. This humidity reducing/perspiration removal system removes sweat while maintaining a secure adherence. The term *dynamic air exchange* is used to describe the negative gauge pressure airflow feature of the system.

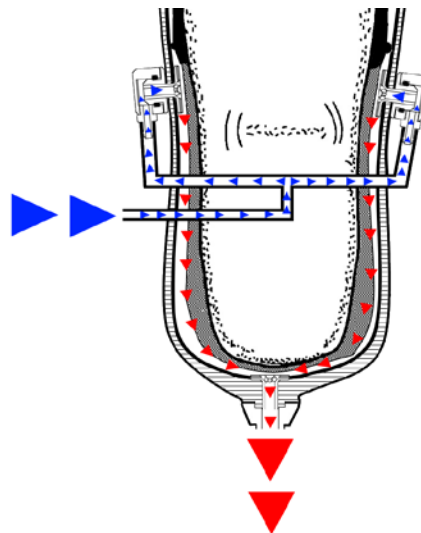


Figure 2: External fresh air (blue arrows) flows along the skin surface (red arrows) to a distal collection port.

The SOW identifies three tasks for this project which are described in detail below.

Task 1: Develop the novel prosthetic airflow control system

The novel prosthetic airflow control system consists of a battery-operated negative gauge pressure pump, a solenoid valve, and associated control electronics. When the solenoid valve is closed, the negative gauge pressure pump maintains a vacuum pressure holding the liner and limb in secure adherence. The minimal amount of vacuum pressure needed to hold the liner on the limb is a function of the weight of the prosthesis divided by the cross-sectional area of the residual limb near the distal end. When the solenoid valve is opened by either a push button located on the pump enclosure or by a remote control fob, *dynamic air exchange* occurs: outside air flows through the flexible tubing to the proximal airflow ports. The vacuum pressure then draws this air through the moisture-wicking sock towards the distal air flow port achieving moisture removal and a reduction of humidity in the regulated environment around the residual limb. Perspiration and moisture-laden air is then expelled from the prosthesis.

The work for this task included: (1) completing the design of the control electronic circuit boards, (2) purchasing the pumps, solenoid valves, and electronic components, (3) fabricating the control electronic circuit boards, (4) assembling the completed systems, and (5) testing their operation on the bench. An external housing to mount and protect the electronic components used to control the system was also designed and fabricated (see Figure 3). This external housing and electronics assembly is attached externally to the prosthetic socket.

The milestone for this task was the manufacture of three novel prosthetic airflow control systems for use in human subject testing. This milestone was achieved and these components were used in our human subject tests.

Task 2: Develop the test prostheses

The test prosthesis includes a number of components: (1) unique moisture-wicking sock with a molded proximal seal worn between the skin and the prosthetic liner, (2) a novel prosthetic liner fitted with proximal and distal air flow channels, and (3) the prosthetic socket assembly.

To use the novel prosthesis, an amputee first dons the sock over their residual limb (see Figure 4). The sock provides a transport mechanism for both air and perspiration. When in operation, the sock also distributes the vacuum pressure to provide secure adherence between the skin and liner irrespective of the presence of moisture, thereby reducing or eliminating the undesirable relative movement between the two, also known as “pistoning.” To achieve the vacuum, a silicone seal is molded and integral with the proximal edge of the socket (see Figure 5).

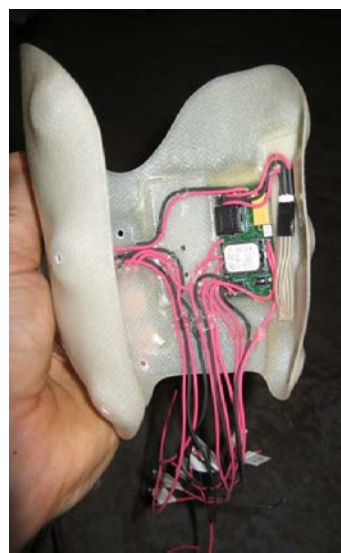


Figure 3: External housing.



Figure 4: Donning of the unique sock over the residual limb.



Figure 5: Moisture-wicking sock shown with proximal silicone seal.

The prosthetic liner, with proximal and distal ports, is then donned over the sock (see Figure 6).

Flexible tubing connects the proximal airflow snap ports to a user-operated solenoid valve that allows outside air to enter the system upon demand. The distal airflow channel, which is comprised of a hollow locking pin, is connected to the battery-operated pump and controller (see Figure 7).



Figure 6: Prosthetic liner with proximal and distal (thru pin) air flow ports.



Figure 7: Medial, anterior, lateral, and posterior views (from left to right) of the test prosthesis.

The work for this reporting period included: (1) human subject measurement, fabrication of sock molds, fabrication of socks, liners, and sockets for each enrolled participant, and (2) assembling the completed systems.

The milestone for this task was the manufacture of six novel prosthetic airflow control systems for use in human subject testing. The plan included re-using the components of the prosthetic air flow system from the first three units for use in the second three units. This milestone was achieved and these assemblies were used in our human subject experiments

Task 3: Conduct human subject experiments.

The objective of our human subject test was to measure and compare the performance of the novel prosthesis with the current standard-of-care (total surface bearing suction socket). The methods, results, and a discussion are presented below, followed by a description of the milestones for this task.

Methods

The study protocol was reviewed and approved by the Veterans Affairs Puget Sound Health Care System's Institutional Review Board and the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO). Informed consent was signed by each subject protocol prior to participating in the study.

Participants

Seven transtibial, unilateral amputees of traumatic were recruited using the following inclusion criteria: (1) between 18 and 70 years of age, (2) fit with and used a prosthesis for at least six months, (3) wore their prostheses at least six hours a day, (4) able to ambulate without upper extremity aids, and (5) able to walk on a treadmill at a steady, self-selected pace for at least 30 minutes. Amputees were excluded if they had vascular problems, pain while walking, ulcerations, tumors, or a history of tumors.

Prosthetic Limb Systems

Each participant wore two study-specific prosthetic limbs: a novel, dynamic air exchange vacuum socket and a standard-of-care suction socket. The novel dynamic air exchange (DAE) prosthesis included: a custom moisture-wicking textile sock with a proximal elastomeric seal, a modified-pin lock elastomeric liner, and a total contact socket with a custom-designed, battery-operated negative gauge pressure generating device and associated components attached to the socket exterior. The DAE system uses a small pump (CTS Series; Parker) attached to the liner ports (four proximal, one distal) to obtain a slight proximal-to-distal pressure differential across the residual limb for secure adherence. A solenoid valve (Clippard, Parker), opened by a user operated push-button, allowed air flow through the sock weave from proximal to distal, ventilating the subject's skin. The standard-of-care suction (Suction) prosthesis included: a cushioned elastomeric liner, a total surface bearing suction socket with an expulsion valve, and an elastomeric sleeve. For both systems, the socket was attached to an aluminum pylon and a Seattle Lightfoot2 (Truelife, Poulsbo, WA). When needed for residual limb volume control, an additional wool or synthetic sock was worn over the liner to improve fit.

Experimental Protocol

Amputee participants were randomly assigned to begin the study with either the DAE or Suction prosthesis. Subjects were fit with each system just prior to an acclimation period using fitting well-established procedures performed by a certified prosthetist. After a comfortable fit was achieved, subjects were given a step activity monitor (StepWatch3; Orthocare Innovations), a digital voice recorder, and instructions on their use at home. The StepWatch measures the number of steps taken by the prosthetic limb as the participants go about their normal daily activities. The voice recorder was provided to explain why they turned on the dynamic air exchange feature (DAE prosthesis only) and for the opportunity to record their observations and

critiques about the limb. The data was used to determine if there was a relationship between step activity, activity intensity, and/or duration and how the active cooling was operated by the subject.

Subjects returned to our motion analysis laboratory to participate in a two hour data collection session. After the data collection session, subjects switched to the other study prosthesis. Following the second, one-week acclimation period, subjects again returned to the motion analysis laboratory for a second data collection session.

Laboratory Assessment

Upon entering the lab for the data collection session, subjects turned in their voice recorder for transcription and their self-selected walking speed was determined while walking down a straight hallway. The time to walk 20 meters was averaged from three trials. This walking speed was used for the treadmill walk portion of the protocol. Subjects were asked to change into a polypropylene insulating layer (long-sleeved shirt and pants), a polar fleece pull-over and a polar fleece cap and a moisture wicking sock with molded proximal seal (for novel system only) that were provided. To measure pistoning (movement with the socket), standard anthropometric measurements were taken for each individual as required for static and dynamic modeling. We then photographed each subject's residual limb before and after 15 minutes of wearing bearing to make note of redness and other residual limb change that accompany weight bearing in their prosthesis. No unique, subject-identifying photographs were taken. For the DAE prosthesis only, relative humidity in the motion analysis lab was measured to help correct for the moisture collected in the desiccant and moisture trap resulting from atmospheric humidity.

Following the photographs, two small thermistors (model MA 100BF; Thermometrics, Edison, NJ) were taped to the subject's residual limb, after which the subject donned the prosthesis over the thermistors. The thermistors were powered and sampled at 0.125 Hz with a portable data acquisition unit (SmartReader Plus 8; ACR Systems Inc., Surrey, British Columbia, Canada). To maintain a sealed environment, the thermistors exited the proximal edge of the liner and sealed with silicone to prevent air leaks. The two thermistors were taped to the skin over the medial and lateral borders of the gastrocnemius muscle on the residual limb. The paired thermistor wires will be routed up the limb, one pair to the medial side and one pair to the lateral side of the knee to prevent wire impingement from damaging both sensors.

While one investigator attached the thermistors, another investigator weighed the moisture-wicking sock (novel system only) and weighed and then attached a desiccant trap (custom designed drying tube employing Drierite desiccant; W.A. Hammond Drierite Co. Ltd., Xenia, OH) to the distal port tubing. After donning the limb, sixteen reflective markers were placed on each subject's hips, legs and feet in locations consistent with the Vicon Plug-In-Gait lower-body model (Oxford Metrics, England) for the pistoning data collection. Further, two marker triads (six reflective markers) were placed on the subject's prosthetic side just above the socket on the lateral side of the thigh (thigh triad) and one on the lateral "ear" of the socket (socket triad).

Fully instrumented, each subject performed the following activities in the laboratory: rest while seated for 30 minutes, walk (at self-selected speed) on a treadmill (Bertec Instrumented Treadmill, Bertec Corporation, Bertec, OH) for 30 minutes, then rest while seated for 30

minutes. For the session with the DAE prosthesis, subjects were asked to active the dynamic air exchange feature at the beginning of the exercise bout and have it remain on until the completion of the second rest period. After the completion of the rest-walk-rest sequence, the thermistors and reflective markers were carefully removed, the subject's limb and inside of the liner were wiped down with paper towels and weighed, and the desiccant trap and moisture-wicking sock was removed and weighed. The weight of the desiccant and moisture trap was corrected for the environmental humidity in the laboratory.

Pistoning was collected using an infrared twelve-camera motion analysis system (Vicon MX; Oxford Metrics, Oxford, England) while standing in place and shifting their weight back and forth from one foot to the other. Subjects will be instructed to stand in place, knees and "ankles" locked in position and shift their weight from side-to-side. This movement is typically used in the clinic to assess socket fit. Pistoning data was collected at three points during the session: just prior to the exercise bout (DAE not operating), at the 15-minute mark of the exercise bout (DAE operating), and at the 30-minute mark of the exercise bout (DAE operating).

Pistoning (movement) within the prosthetic socket while walking was calculated by measuring the change in the resultant distance between a three reflective markers placed on the lateral "ear" of socket (socket triad) and a marker triad placed on the thigh above the socket (thigh triad). Pistoning was quantified as the difference between the resultant distance along the long axis of the femur when the limb was un-weighted (residual limb was maximally "pulled" out of the prosthetic socket) and when the limb was fully supporting body weight (residual limb will fully seated within the socket). Triads at the knee and thigh allowed us to imbed a coordinate axis at each location to ensure that we could visualize the change in resultant displacement along the long axis of the femur. By using the triads at the thigh and the knee, motion between the residual limb and socket can also be quantified in the frontal and transverse planes during midstance to better define the quality of socket fit during loading.

At the end of the data collection session, subjects had their StepWatch activity monitor data downloaded and were then asked to fill out two questionnaires. Subjects then visited the Prosthetics Department to be fir for their second study limb. The laboratory session required three hours to complete.

Questionnaires

The subjects' opinions of the study prosthesis were assessed with two questionnaires. The first was a custom questionnaire (see Appendix B) to assess the prostheses thermal and moisture management acceptability. It consisted of six questions to be scored from 0 to 10. The second questionnaire was the well-known, standardized questionnaire Prosthesis Evaluation Questionnaire (PEQ; Legro et al., 1998) for which three subscales were scored (Ambulation, Frustration, and Residual Limb Health) on scale from 0 to 100. The questions were modified from the original, one month period of experiences to a one week period due to the one week acclimation period of this study (see Appendix C). Both questionnaires were administered during the laboratory visits.

Data Analysis

To quantify the amount of moisture removed from the novel system, the desiccant and moisture trap were weighted pre- and post-testing and the relative humidity of the lab was used to help correct for weight due to moisture from the atmosphere. The difference in weight of the moisture-wicking sock pre- and post-test combined (DAE prosthesis only) with the tare weight of paper towels used to wipe down the limb and inner surface of the liner allowed us to calculate the amount of sweat remaining inside the limb. Weight was used to test the hypothesis (H_1): *Transtibial amputees wearing a DAE prosthesis will have a measurable amount of perspiration removed during a 30-minute exercise bout followed by a 30-minute rest period.*

The change in the resultant distance along the long axis of the femur for three steps of 10 cycles from the weight shifting motion were processed using Vicon's Polygon program and Matlab (MathWorks, Natick, MA). This data enabled us to test the hypothesis (H_2): *Transtibial amputees wearing a DAE prosthesis will exhibit less limb pistoning while walking and shifting their weight laterally from side-to-side after exercise than when wearing a Suction socket (standard-of-care).*

By comparing the tabulated questionnaire scores across prostheses, we anticipated testing the Hypothesis (H_3): *Transtibial amputees will perceive greater positive thermal and moisture acceptability after exercise when wearing a DAE prosthesis than when wearing a Suction socket (standard-of-care).*

To measure changes in skin temperature, the average maximum or minimum temperature for each thermistor during the rest-exercise-rest sequence was noted and a difference calculated. This data was downloaded from the portable data loggers and analyzed and presented using temperature plots generated in Matlab. This data enabled us to test the hypothesis (H_4): *Transtibial amputees wearing a DAE prosthesis will have no greater limb skin temperatures after exercise than when wearing Suction prosthesis (standard-of-care).*

Four within-subject, repeated measures analyses of variance (ANOVA) were planned to explore the hypotheses under two different conditions (DAE prosthesis v. Suction prosthesis). The experiment-wise significance was set *a priori* at an alpha level of $p < 0.05$. A Bonferroni correction would be used for multiple tests with linear contrast *post hoc*. The analysis was conducted using JMP Software (SAS Institute Inc., Cary, NC).

Results

Subject Demographics

Eight male transtibial, unilateral amputees provided informed consent (see Appendix A for human subject enrollment table). Of the eight enrolled, four completed the protocol as planned, one was experienced a weight gain and had fit issues half way through the protocol. This subject was enrolled again, fit with a larger prosthesis, and completed the part of the protocol they had difficulties with, and was then withdrawn. Two other subjects were withdrawn: one became unreachable and one due to concerns about obesity and structural margins of safety of the prototype. Of the five subjects that completed the entire protocol, three amputations were of traumatic etiology and for two the cause was secondary to infection. All subjects met the

inclusion criteria and were able to walk on the treadmill continuously for the 30 minutes in the test. Two subjects were not able to do the test in consecutive weeks for personal reasons. For these two cases, we waited until they were able to commit to the week of acclimation wear time and the test. The sample population can be described as 44.4 ± 15.4 years of age, 89.2 ± 17.9 kg body mass; 182.9 ± 5.0 cm height (see Table 1).

Table 1: Demographics of the five participants.

| Subject | Age (yr) | Gender | Amputated side | Body Mass (kg) | Height (cm) | Time since amputation (yrs) | Etiology |
|----------------|-----------------|--------|----------------|-----------------|---------------|-----------------------------|-----------|
| 1 | 33 | M | Left | 72.6 | 177.8 | 9 | Traumatic |
| 3 | 45 | M | Left | 86.2 | 180 | 18 | Infection |
| 4 | 51 | M | Right | 118.8 | 191 | 3 | Infection |
| 5 | 66 | M | Left | 89.8 | 183 | 39 | Traumatic |
| 6 | 27 | M | Left | 78.5 | 182.9 | 2 | Traumatic |
| Mean \pm Std | 44.4 \pm 15.4 | - | - | 89.2 \pm 17.9 | 182.9 \pm 5 | 14.2 \pm 15.3 | - |

Perspiration

The DAE prosthesis expelled 0.67 g sweat and retained 1.09 g in the prosthesis while the Suction prosthesis retained 0.97 g sweat (see Table 2). *Transtibial amputees wearing a DAE prosthesis had a measurable amount of perspiration removed during a 30-minute exercise bout followed by a 30-minute rest period.*

Table 2: Perspiration totals (n=5) that remained or was expelled (for DAE) from the study prostheses.

| Location of Sweat | Sweat Weight (g) mean \pm std |
|----------------------------|---------------------------------|
| Retained in DAE Socket | 1.09 \pm 0.90 |
| Expelled from DAE Socket | 0.67 \pm 0.38 |
| Retained in Suction Socket | 0.97 \pm 0.75 |

Pistoning

Overall results, calculated from the entire data set, show the DAE pistoning was ~ 10 mm versus the Suction pistoning at ~ 6 mm (see Table 3; note that subject one did not have markers placed on the greater trochanter preventing this analysis. This subject was excluded from the results). This calculation was based on a correction for an unexpected artifact in the results. Oddly, a measurement of pistoning, using equivalent markers on the sound limb, was observed. It is unclear what is causing this artifact and is the subject of further investigation. In the interim, to account for this issue, pistoning was calculated as the difference between prosthetic and sound limbs since the sound limb cannot piston.

Since only four subjects were included in the data set, no statistical analysis was performed. However, a difference of ~ 4 mm between the two study prosthesis is not thought to be clinically significant. *Transtibial amputees wearing a DAE prosthesis exhibited equivalent limb pistoning while shifting their weight laterally from side-to-side after exercise as when wearing a Suction prosthesis (standard-of-care).*

Table 3: Overall pistoning while wearing the study prostheses (n=4).

| Socket | Prosthetic Limb | Sound Limb | Difference |
|---------|-----------------|------------|------------|
| DAE | 13.7 ± 2.8 | 3.1 ± 2.0 | 10.6 |
| Suction | 11.3 ± 3.0 | 4.5 ± 2.0 | 6.9 |

Comparing the results from the different data collection times in the protocol, pistoning appeared to increase slightly from baseline (before exercise), to the mid-point time (15-minute mark), and to the end of exercise (30-minute mark) (see Table 4).

Table 4: Pistoning while wearing the study prostheses (n=4) at different times in the protocol.

| Socket | Prosthetic Limb | Sound Limb | Difference |
|--|-----------------|------------|------------|
| Prior to exercise (DAE not operating) | | | |
| DAE | 12.6 ± 1.8 | 2.8 ± 2.1 | 9.8 |
| Suction | 10.9 ± 3.8 | 4.7 ± 1.9 | 6.2 |
| At the 15-minute mark of the exercise bout (DAE operating) | | | |
| DAE | 13.3 ± 2.2 | 2.9 ± 1.7 | 10.4 |
| Suction | 11.1 ± 2.5 | 3.7 ± 1.2 | 7.4 |
| At the 30-minute mark of the exercise bout (DAE operating) | | | |
| DAE | 15.1 ± 3.6 | 3.6 ± 2.2 | 11.5 |
| Suction | 11.9 ± 2.7 | 5.0 ± 2.6 | 6.9 |

Skin Temperatures

Which study prosthesis was wearing appeared to have little influence on residual limb skin temperatures. The residual limb skin temperature generally stayed constant during the first rest period, increased substantially during walking activity, and fell gradually during the final rest (see Table 5 and Figures 8 and 9). *Transtibial amputees wearing a DAE prosthesis had no greater limb skin temperatures after exercise than when wearing Suction prosthesis (standard-of-care).*

Table 5: The change in residual limb skin temperature (°C; mean ± standard deviation) while wearing the study prostheses (n=5) at different times in the protocol.

| Socket | Medial Gastrocnemius | Lateral Gastrocnemius |
|---|----------------------|-----------------------|
| From the beginning to the end of the first rest. | | |
| DAE | -0.02 ± 0.39 | 0.02 ± 0.32 |
| Suction | 0.03 ± 0.27 | 0.47 ± 0.33 |
| From the end of the first rest to the maximum temperature reached | | |
| DAE | 3.13 ± 0.76) | 2.83 ± 0.41 |
| Suction | 3.39 ± 0.71) | 2.85 ± 0.75 |
| From the maximum temperature reached to the end of the final rest | | |
| DAE | -1.09 ± 0.17 | -0.93 ± 0.50 |
| Suction | -1.10 ± 0.05 | -0.79 ± 0.33 |

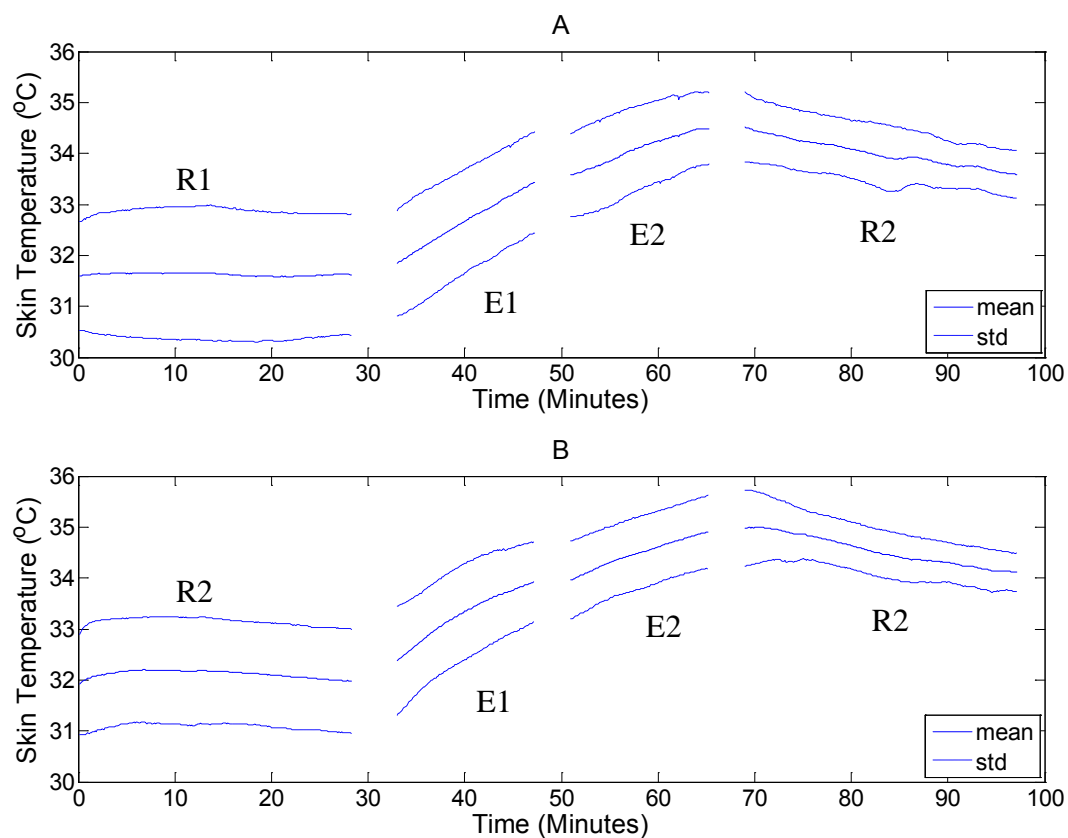


Figure 8: The mean medial gastrocnemius skin temperature while donning the DAE (Figure 8A above) and Suction (Figure 8B below) systems during an initial 30-minute rest (R1), a 30-minute walk with a short break in the middle to acquire pistoning data (E1 and E2), and a final 30-minute rest (R2).

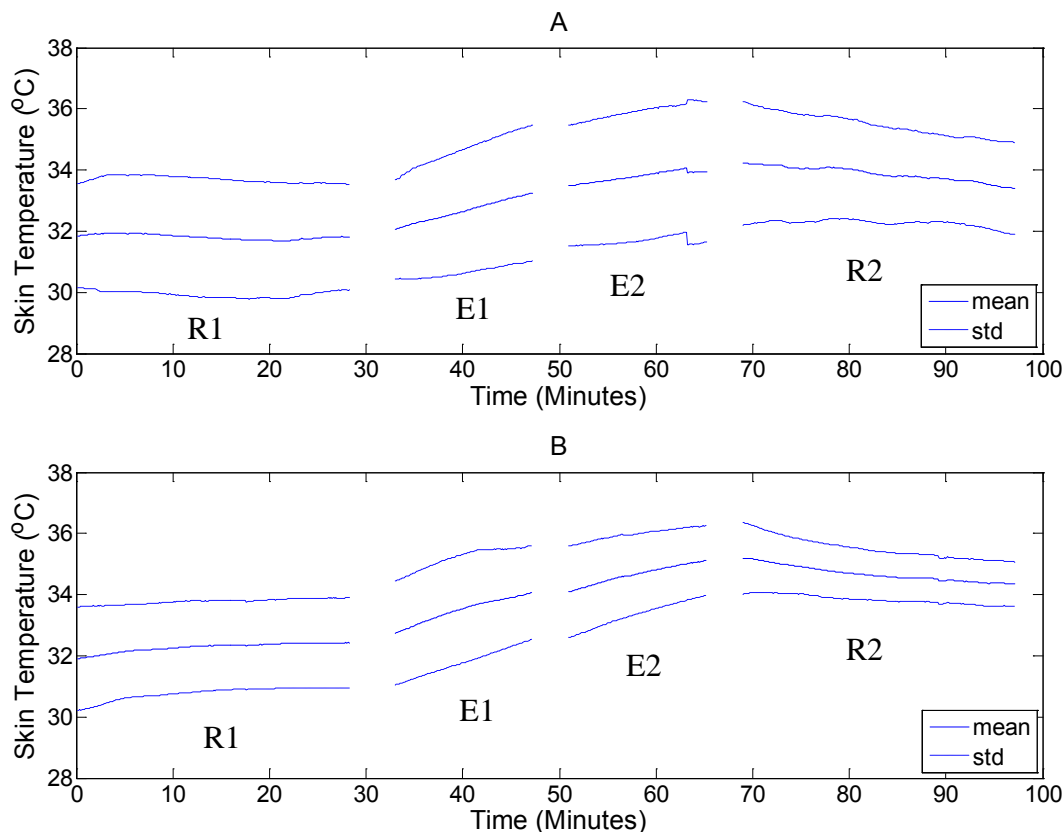


Figure 9: The mean lateral gastrocnemius skin temperature while donning the DAE (Figure 9A above) and Suction (Figure 9B below) systems during an initial 30-minute rest (R1), a 30-minute walk with a short break in the middle to acquire pistoning data (E1 and E2), and a final 30-minute rest (R2).

Step Counts

The step activity data shows that the sample population was highly active individuals who would likely benefit from improved moisture management and prosthetic limb adherence technologies. Subjects were slightly more active in the Suction prosthesis than the DAE prosthesis (see Table 6).

The transcribed subject notes provide some explanation for the observed differences in step counts. Subject 1 had bruising at the distal end of his residual limb and a lot of trouble donning the DAE prosthesis. His frustration and discomfort may account for the observation that he had more than three times the amount of total weekly steps while in the Suction prosthesis than the DAE prosthesis. Subject 4 was moving during the Suction prosthesis acclimation period and injured himself (not study related), which may explain why he stepped more than four times the amount while wearing the DAE prosthesis as opposed to the Suction prosthesis. During the initial fitting, Subject 6 inquired about wearing the DAE prosthesis while running. While our analysis suggests the limb could easily withstand running loads, we have not performed mechanical tests to confirm failure loads. We asked the subject to only use the DAE prosthesis

for walking and biking. Upon completion of the protocol, the subject admitted that he did not wear it to work because he worried it would not hold up to the rigors of his job. This may explain the very low step count while wearing the DAE prosthesis. The input from the two individuals would had trouble with the DAE prosthesis during the acclimation period helped improved the design as immediate changes were made to the distal locking-pin mechanism on how to improve the design of the leg and has resulted in changes.

Table 6: Daily and weekly step count of the prosthetic leg.

| Subject | Average Daily Step Count | | Total Weekly Step Count | |
|----------------|--------------------------|-------------------|-------------------------|---------------------|
| | DAE | Suction | DAE | Suction |
| 1 | 1,634 | 2,659 | 6,554 | 21,274 |
| 3 | 3,361* | 3,948 | 26,891* | 31,583 |
| 4 | 1,625 | 364 | 12,983 | 2,909 |
| 5 | 6,216 | 6,955 | 49,725 | 55,642 |
| 6 | 199 | 4,320 | 1,594 | 34,557 |
| Mean \pm Std | 2,607 \pm 2,308 | 3,649 \pm 2,411 | 19,549 \pm 19,358 | 29,193 \pm 19,285 |

* The average daily and total weekly step counts for Subject 3 while donning the initial tight DAE system were 3,164 and 25,312, respectively.

Subjective Comments

Results from the custom questionnaire suggest the subjects generally thought the DAE prosthesis did a better job at providing thermal comfort and managing moisture accumulation (see Figure 10). On average, the subjects scored the Suction prosthesis over 6 points higher than the DAE prosthesis for their residual limb getting too hot and sweaty during activity (see Figure 1, question A) and over 5 points higher for having to stop and dry off their residual limb when wearing the prosthesis (see Figure 10, question E). This suggests the subjects perceived that the DAE prosthesis managed moisture and heat more effectively than the Suction prosthesis, which is also evidenced by the fact that subjects scored the DAE prosthesis approximately 4 points higher than the Suction prosthesis for its ability to keep the residual limb at a very comfortable temperature (see Figure 10, question B). Perception of pistoning inside the socket or loss of adherence was highly variable (see Figure 10, question C error bars) but on average scored moderately low for both study prostheses. Two subjects strongly disagreed, and one moderately disagreed that the Suction prosthesis caused them to be more active (see Figure 10, question D).

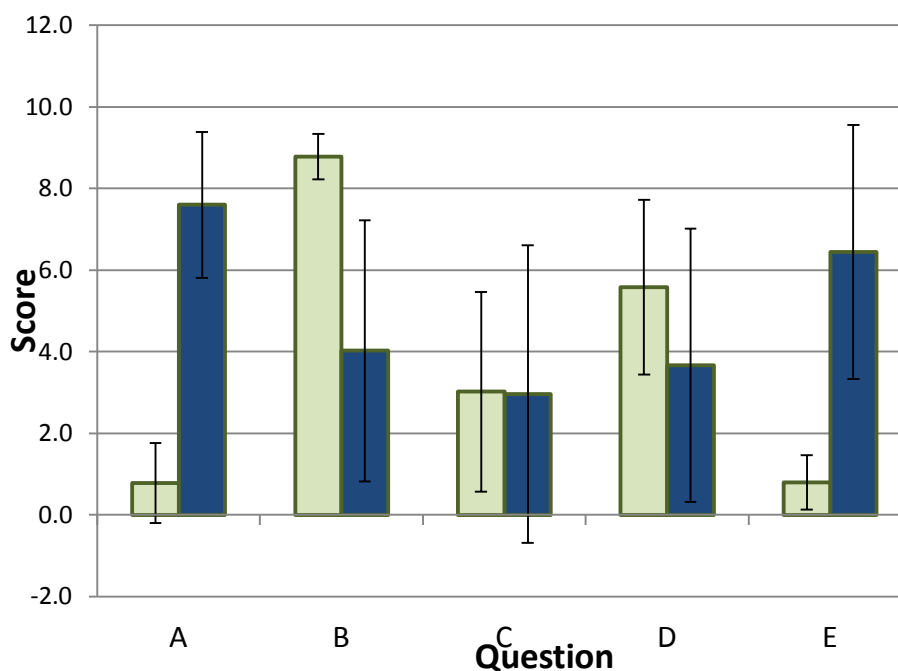


Figure 10: Results from the thermal and moisture acceptability questionnaire. The DAE prosthesis is the light blue bars on the left and the Suction prosthesis is the dark blue bars on the right for each question. The questions were scored from Strongly Disagree (0) to Strongly Agree (10) and included:

- A. My residual limb gets too hot and sweaty when I am active in this socket system.
- B. I find this socket system keeps my residual limb at a very comfortable temperature.
- C. My prosthesis feels like it is sliding up and down or falling off when I am active.
- D. I have been more active than normal as a result of this prosthesis.
- E. I have to stop and dry my residual limb when wearing this prosthesis.

Results from the Prosthesis Evaluation Questionnaire (PEQ) were separated and averaged for three subscales: Residual Limb Health, Frustration, and Ambulation. Overall, the subjects reported less frustration while wearing the Suction prosthesis and better residual limb health and ambulation while wearing the DAE prosthesis (see Figure 11). Subjects consistently reported less sweat inside their prosthesis and over half reported less odor while wearing the DAE prosthesis. Two subjects were particularly displeased with the amount of sweat and odor inside their Suction prosthesis. In general, subjects reported maintaining good skin health with both systems. Unfortunately, one subject (Subject 1) bruised the distal end of his residual limb while donning the DAE prosthesis and another (Subject 3) developed a quarter-sized blister while wearing the Suction prosthesis during each subject's acclimation week (both anticipated potential problems with prosthetic limbs in general). Subject 4 developed a small scrap from a thermistor while testing his first study prosthesis (DAE) and subsequently reported low scores regarding skin health while wearing the Suction prosthesis. It is unclear if those scores reflect the existence of the abrasion or not. The results regarding frustration with the system were highly variable, but in general the subjects thought the Suction prosthesis was less frustrating than the

DAE prosthesis. The most frustrated user of the DAE prosthesis was the first subject, who provided extremely valuable feedback that resulted in changes to the design and the instructions we gave to subsequent subjects when first introducing the limb. For the first subject, it was very difficult to align the pin with the lock. The pin was modified and we notified the subsequent subjects to be mindful of this issue and be patient when donning the socket. Ambulation scores were similar for all questions except the ability to walk up stairs, on the street or sidewalk, and slippery surfaces, in which subjects generally had more confidence in the DAE prosthesis than the Suction prosthesis. One subject verbally noted that the bulk of the suspension sleeve worn over the Suction prosthesis made ascending stairs difficult.

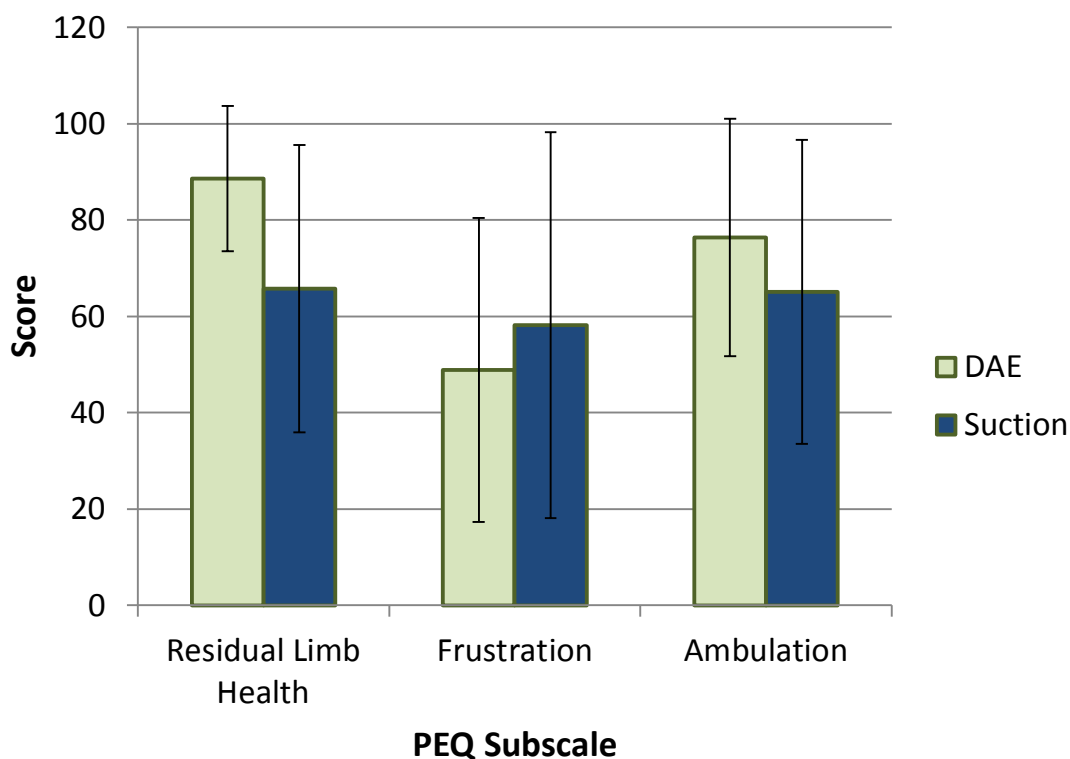


Figure 11: Results from the Residual Limb Health, Frustration, and Ambulation subscales of the Prosthesis Evaluation Questionnaire (PEQ). The subscales scored on a scale of 0 (problematic) to 100 (optimal).

All subjects wore each study prosthesis for a week prior to the lab experiment and were provided with a voice recorder to make observations. The observational data collected during the acclimation week and prior to the start of the laboratory tests was organized *post-hoc* into four themes (see Table 7) including: Comfort, Ease of Use, Stability, and Miscellaneous. The overall consensus was varied for each theme, but unified concerns/comments follow. Three subjects (Subjects 4, 5, and 6) thought the DAE prosthesis handled moisture inside the limb better than the Suction prosthesis. One particularly active subject (Subject 6) mentioned that a moist textile sock against his skin is far more comfortable than the feeling of wet silicone liner. Another subject (Subject 5) mentioned that he immediately felt cooling when he opened the solenoid

valve. Unfortunately, one subject (Subject 3) developed a friction blister at the distal end of his residual limb when he claimed he got really sweaty moving while wearing the suction socket. Multiple subjects felt that the added sleeve on the suction socket helped reduce pistoning (Subject 1) and improving stability in the socket (Subject 1, 3 and 5), but added bulk (Subjects 1, 3, 4, and 6) and decreased range of motion in the knee (Subjects 1, 3, 5, and 6). One subject (S1) was very frustrated donning the DAE prosthesis because the modified pin caught on the rim of the lock. This was not expressed as a concern by any other subjects, likely because we advised them on the potential difficult donning the socket. This subject also enlightened us to the fact that the leg did not fit under his pants, which resulted in a redesign of how the components were configured on the outside of the socket and also brought about the additional design and manufacture of an over-mold that housed and protected the pump, wiring, and solenoid valve on the exterior of the socket. Finally, three subjects (Subjects 3, 4, and 6) had issues with how noisy the pump was when the solenoid valve was opened to allow airflow over the limb.

Table 7: Observational data recorded regarding their experiences.

| Theme | DAE | Suction |
|------------------------|--|---|
| Comfort | <ul style="list-style-type: none"> • Limb felt drier (S4, S5, S6) • Felt comfortable (S4, S5) • Lightweight (S6) • Deals with sweat better/more comfortable than liner against skin (S5, S6) • Feels cool when opened the solenoid valve (S5, S6) | <ul style="list-style-type: none"> • Extra outer sleeve irritates skin near top of leg and causes increased sweating (S1) • Bulky outer sleeve (S1, S3, S4, S6) • Warm (S6) • Heavy (S6) • Comfortable socket and liner. |
| Ease of Use | <ul style="list-style-type: none"> • Difficult to don due to pin alignment (S1) | <ul style="list-style-type: none"> • Decreased range of motion (S1, S3, S5, S6) |
| Stability & Suspension | <ul style="list-style-type: none"> • Notices and likes vacuum (S3) • Good suspension (S6) | <ul style="list-style-type: none"> • Increased stability of knee (S1) • Decreases pistoning (S1) • Great adherence (S3, S5) |
| Miscellaneous | <ul style="list-style-type: none"> • Noisy (S3, S4, S6) • Limb does not fit under all pants (S1, S6) | <ul style="list-style-type: none"> • A blistered form on distal end of residual limb when got really sweaty (S3) • Worried about hole for valve (S5) |

In summary, the subjective experience of the subjects was positive. Due to the large variances in the questionnaire data and the small sample population, no statistical analysis was attempted. The results suggest that *Transtibial amputees perceived greater positive thermal and moisture acceptability after exercise when wearing a DAE prosthesis than when wearing a Suction prosthesis (standard-of-care).*

Experimental Tasks and Milestones

The scope of activity task of conducting a human subject test had four milestones: (1) obtain and maintain approval from all regulatory bodies, (2) recruit and enroll six transtibial amputees, (3) conduct tests and analyze data, and (4) publish results.

The continuing milestone to obtain and maintain approval from all regulatory bodies engaged in this research has been met. We have maintained approval from the Veterans Affairs Puget Sound Health Care System (VAPSHCS) Institutional Review Board (IRB) and the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO). We plan to close this study to further enrollment but maintain approval for data analysis purposes. At no time will human subjects research be conducted without approval.

The milestone to enroll six transtibial amputees has been met. Eight transtibial amputees provided informed consent and were enrolled in the study (see Appendix A for human subject enrollment table and status of each enrollee). Six study prostheses were assembled. Five transtibial amputees completed all data collection elements of the protocol. Three amputees were withdrawn. No participants remain in the protocol and all study prostheses have been returned. All participants were returned to their as-prescribed prosthesis.

The milestone to conduct tests and analyze data has been met. Details regarding the results are provided in the Research Results section below.

The milestone to publish our results has also been met. Dr. Klute presented selected results (i.e., skin temperatures and expelled sweat) in a presentation titled “In-socket moisture management using negative gauge pressure” in an invited session at the American Academy of Orthotists and Prosthetists 39th Annual Meeting and Scientific Symposium, held in Orlando, FL, on February 23, 2013. The audience consisted of prosthetists, clinicians, amputees, and researchers. Based on the number of questions from the audience, the interest in reducing temperature-related discomfort and sweat removal is high among both practitioners and patients. As this was an invited session, the topic is also of interest among researchers and those who are interested in research results.

We expect to produce two peer-reviewed manuscripts: one describing the intervention and how it functions (a methods paper) and one describing its performance. One option for the performance manuscript, for which we have submitted an abstract for consideration in February 2013, is publication in a special topic issue of Clinical Orthopaedics and Related Research (known as a CORR symposium). The topic for this special issue is Amputations and related issues and technologies.

III. KEY RESEARCH ACCOMPLISHMENTS

The major research findings for the period July 18, 2011 through March 17, 2013 include:

- The Dynamic Air Exchange (DAE) prosthesis was able to expel a significant amount of perspiration during the 30-minute treadmill walk at self-selected speed.
- The DAE prosthesis had similar residual limb movement (~10 mm) relative to the prosthetic socket (i.e., “pistoning”) as the Suction prosthesis (~6 mm). The difference between the two study prostheses of ~ 4 mm is not thought to be clinically significant.
- The DAE prosthesis had negligible effects on residual limb skin temperatures when compared to the Suction prosthesis. For both prostheses, the residual limb skin

temperature generally stayed constant during the first 30-minute rest period, increased substantially (~3 °C) during the 30-minute walk at self-selected speed, and fell gradually (~1 °C) during the final 30-minute rest period.

- The DAE prosthesis was subjectively found to provide desirable benefits with an acceptable burden.

IV. REPORTABLE OUTCOMES

The reportable outcomes for the period July 18, 2011 through March 17, 2013 include:

- A presentation including some of the results from the work conducted as part of this project was presented by Dr. Klute (see Appendix D) to a national audience of prosthetists, clinicians, amputees, and researchers. The citation for this presentation is:

GK Klute, K Bates, JS Berge, W Biggs, C King, “In-Socket Moisture Management using Negative Gauge Pressure” Presented at the American Academy of Orthotists and Prosthetists 39th Annual Meeting and Scientific Symposium, Orlando, Florida, February 23, 2013.

- A grant, whose aims were developed in part from the work conducted as a part of this project, was funded by the Department of Veterans Affairs, Rehabilitation Research and Development Service. The aims of this research include: measuring thermal perception and vasomotor response to thermal stimuli, developing a novel prosthesis with the aid of a unique thermal manikin to simulate the residual limb, and conducting human subject tests to see if the dynamic air exchange induced by this prosthesis can provide thermal relief and expel accumulated sweat. The citation for this grant is:

Skin Temperature Perception and Prosthetic Thermoregulation

Dept. of Veterans Affairs, Rehabilitation R&D Service 7/2012 - 6/2015

I01 RX000901-01 (A9186R) \$825k

PI: Glenn K. Klute, PhD

Aims: The aims of this research include measuring thermal perception and vasomotor response to thermal stimuli, developing a novel prosthesis with the aid of a unique thermal manikin to simulate the residual limb, and conducting human subject tests to see if the dynamic air exchange induced by this prosthesis can provide thermal relief and expel accumulated sweat.

V. CONCLUSIONS

The overall objective of this project was to develop a novel Dynamic Air Exchange prosthesis incorporating a negative gauge pressure moisture management and secure adherence device and compare its performance against the current standard of care (total surface bearing suction prosthesis) in an IRB-approved human subject experiment with transtibial amputees.

The results show the Dynamic Air Exchange (DAE) prosthesis was able to expel a significant amount of perspiration during the 30-minute treadmill walk at self-selected speed.

Approximately 1 g of sweat was removed from the prosthesis during the protocol. The DAE prosthesis exhibited approximately 4 mm more pistoning than a Suction prosthesis (current standard-of-care), the difference was not thought to be clinically meaningful. No effect was found on residual limb skin temperatures. For both the DAE and Suction prostheses, the residual limb skin temperature generally stayed constant during the first 30-minute rest period, increased substantially (~3 °C) during the 30-minute walk at self-selected speed, and fell gradually (~1 °C) during the final 30-minute rest period. Importantly, the DAE prosthesis was subjectively acceptable to the participants as they reported a positive experience.

A future test under a more demanding thermal environment (hot and humid) might reveal even greater differences and stronger participant preferences. While the 30-minute treadmill walk made the participants sweat, no participant lost adherence during the test. A key metric of such a test would be the time to loss of adherence. If the sweat removed by the DAE prosthesis can keep participants from reaching a loss of adherence threshold, we hypothesis they can remain in their prosthesis for significantly longer periods of time.

VI. REFERENCES

MW Legro, GD Reiber, DG Smith, M de la Aguilera, J Larsen, D Boone, “Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life.” Archives of Physical Medicine and Rehabilitation, 1998;79:931-938.

APPENDICES:

This annual report includes three appendices:

- A. Human subjects enrollment table.
- B. American Academy of Orthotists and Prosthetists Presentation
- C. Custom questionnaire to assess thermal and moisture management
- D. Prosthesis Evaluation Questionnaire

Appendix A: Human Subjects Enrollment Table (18 July 2012 – 17 March 2013)

This project, “Negative Gauge Pressure Moisture management and Secure Adherence Device for Prosthetic Limbs”, involves IRB-approved human subject experiments. The enrollment since the beginning of the project (July 18, 2012) through the end of the project (March 17, 2013) is tabulated below (see Table A1).

Table A1: Human subject enrollment and participation through March 17, 2013.

| Patient Population | Enrollment Actual/Target | Withdrawals | Measurements Complete | Prosthesis Fabrication Complete | Protocol Complete |
|---------------------------|---------------------------------|--------------------|------------------------------|--|--------------------------|
| Transtibial Amputee | 8 / 6 | 3 | 7 | 7 | 5 |

The details of participation for each enrolled subject, numbered here in the order in which they were consented, follows:

Subject A1: This subject was consented, measured, fit with the study prosthesis, and completed the experimental protocol.

Subject A2: This subject was consented but administratively withdrawn from the study prior to beginning the protocol due to concerns that the subject was too heavy (330 lbs, 150 kg, body mass index of 45 kg/m² and considered very severely obese) and might be too close to the structural margin of safety for the study prosthesis.

Subject A3: This subject was consented, measured, fit with the study prosthesis, and completed the experimental protocol. Note: this subject gained weight during the dynamic air exchange prosthesis part of the protocol (~15 lbs, ~7 kg) resulting in a less than optimal fit at the time of protocol completion. We decided to re-consent this individual at a later date and make them a new dynamic air exchange socket to repeat this part of the protocol.

Subject A4: This subject was consented, measured, fit with the study prosthesis, and completed the experimental protocol.

Subject A5: This subject was consented, measured, fit with the study prosthesis, and completed the experimental protocol.

Subject A6: This subject was consented, measured, fit with the study prosthesis, and completed the experimental protocol.

Subject A7: This subject was consented, measured, cast, and both study prosthesis have been fabricated. Contact with the subject has been lost and we were unable to re-establish contact. The subject did not have a study prosthesis in their possession and was wearing their as-prescribed prosthesis at last contact. This individual has been administratively withdrawn from the study.

Subject A8: This subject, who is the same as subject 3, was re-consented to repeat the protocol with a new dynamic air exchange socket made to accommodate his change in limb volume associated with his weight gain. The subject was consented, measured, cast, and a dynamic air exchange prosthesis was fabricated. The subject completed the experimental protocol portion involving the dynamic air exchange prosthesis and was then administratively withdrawn so as to forgo testing with the suction socket.

Appendix B: Custom questionnaire to assess thermal and moisture management

Thermal and Moisture Assessment Questionnaire (numerically scored from 0 to 10):

1. My residual limb gets too hot and sweaty when I am active in this socket system.
2. I find this socket system keeps my residual limb at a very comfortable temperature.
3. My prosthesis feels like it is sliding up and down or falling off when I am active.
4. I have been more active than normal as a result of this prosthesis.
5. I have to stop and dry my residual limb when wearing this prosthesis.

Appendix C: Prosthesis Evaluation Questionnaire (PEQ) subscale questions

Prosthesis Evaluation Questionnaire (scored from 0 to 100 on a visual analog scale) questions use the subjects' experiences over the past week. Note the original PEQ uses experiences over the past month.

Residual Limb Health

- 4Q.** Over the past week, rate how much you sweat inside your prosthesis (in the sock, liner, socket).
- 4R.** Over the past week, rate how smelly your prosthesis was at its worst.
- 4S.** Over the past week, rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis.
- 5T.** Over the past week, rate any rash(es) that you got on your residual limb.
- 5U.** Over the past week, rate any ingrown hairs (pimples) that were on your residual limb.
- 5V.** Over the past week, rate any blisters or sores that you got on your residual limb.

Frustration

- 10B.** Over the past week, rate how frequently you were frustrated with your prosthesis.
- 10C.** If you were frustrated with your prosthesis at any time over the past month, think of the most frustrating event and rate how you felt at that time.

Ambulation

- 13A.** Over the past week, rate your ability to walk *when using your prosthesis*.
- 13B.** Over the past week, rate your ability to walk in close spaces *when using your prosthesis*.
- 13C.** Over the past week, rate your ability to walk up stairs *when using your prosthesis*.
- 13D.** Over the past week, rate how you have felt about being able to walk down stairs *when using your prosthesis*.
- 14E.** Over the past week, rate your ability to walk up a steep hill *when using your prosthesis*.
- 14F.** Over the past week, rate your ability to walk down a steep hill *when using your prosthesis*.
- 14G.** Over the past week, rate your ability to walk on sidewalks and streets *when using your prosthesis*.
- 14H.** Over the past week, rate your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or a boat dock) *when using your prosthesis*.

Appendix D: American Academy of Orthotists and Prosthetists Presentation

Dr. Klute presented selected results (i.e., skin temperatures and measurements of perspiration) in a presentation titled “In-socket moisture management using negative gauge pressure” during an invited session at the American Academy of Orthotists and Prosthetists 39th Annual Meeting and Scientific Symposium, held in Orlando, FL, on February 23, 2013.



In-Socket Moisture Management using Negative Gauge Pressure

GK Klute^{1,2}, PhD, K Bates¹, MS, JS Berge¹, MSE,
W Biggs¹, CPO, C King³, CP

¹Dept. of Veteran Affairs

²University of Washington

³Arusha Control, Inc.

Sweaty Limbs Suck!

GK Klute^{1,2}, PhD, K Bates¹, MS, JS Berge¹, MSE,
W Biggs¹, CPO, C King³, CP

¹Dept. of Veteran Affairs

²University of Washington

³Arusha Control, Inc.

Introduction

Clinical Relevance: Patient Discomfort

- 72% identified **heat & perspiration** as responsible for a moderate or worse reduction in quality of life (n=90) (Hagberg & Branemark, 2001)
- 60% reported excessive sweating & 44% reported heat rash (n=119) (Hall, 2007)

Introduction

- Liner and Socket materials are excellent thermal insulators (Klute, 2006)
- Liners are nearly impermeable to moisture (Hachisuka, 2001)

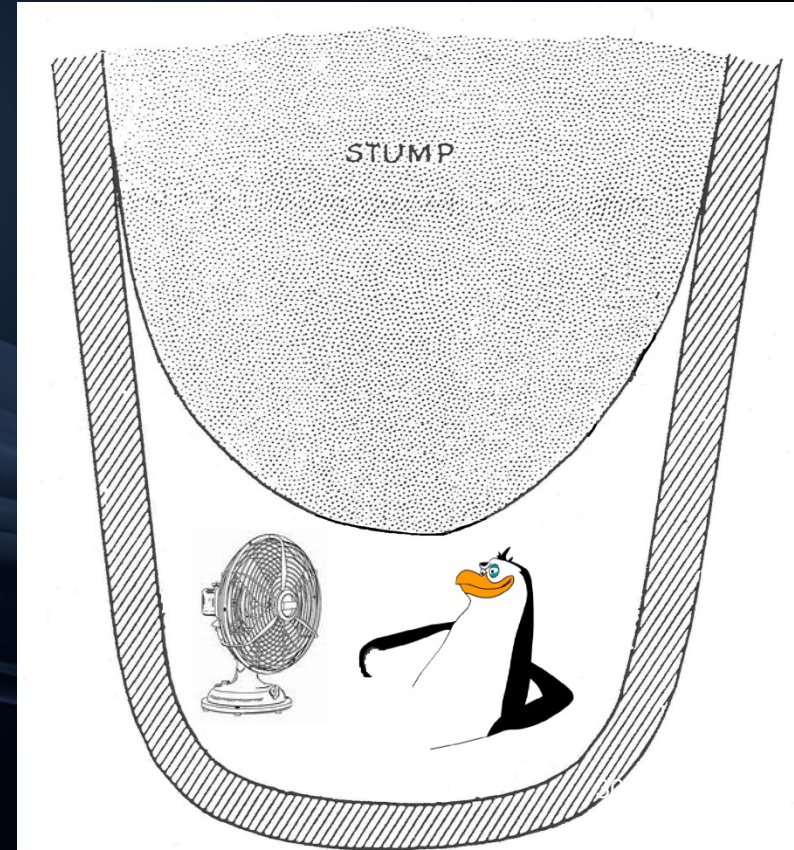
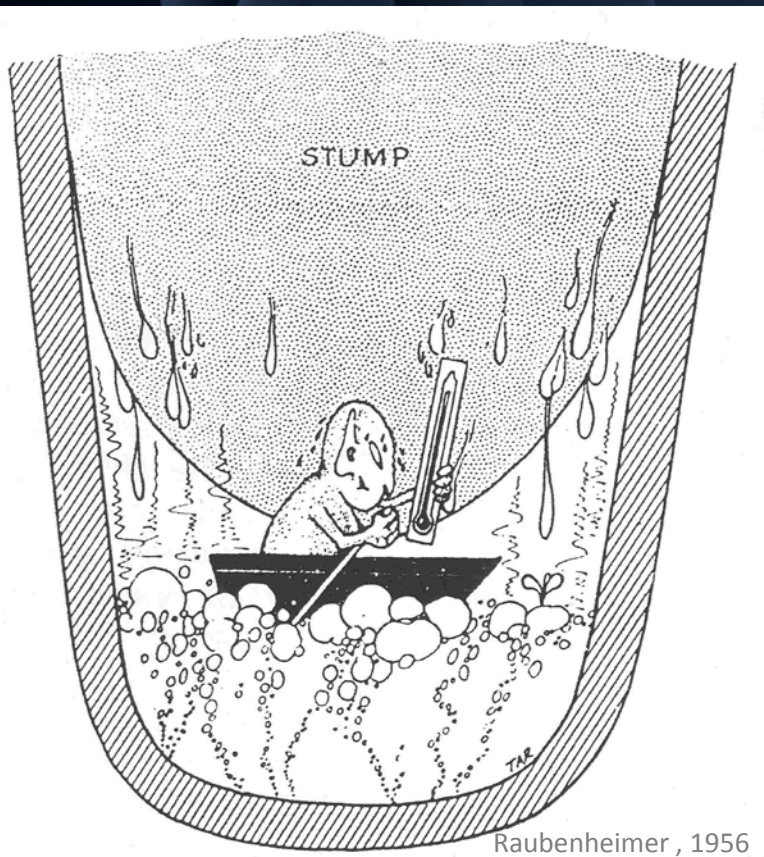
Introduction

- 30 min treadmill walk (Klute, 2006)
 - (n=11 transtibials)
 - +0.4° C donning
 - +2.2° C during 30 minute walk
 - Cooling ½ the rate of warming
- Typical day (Klute, 2007)
 - (n=8 transtibials)
 - +5° C over a day



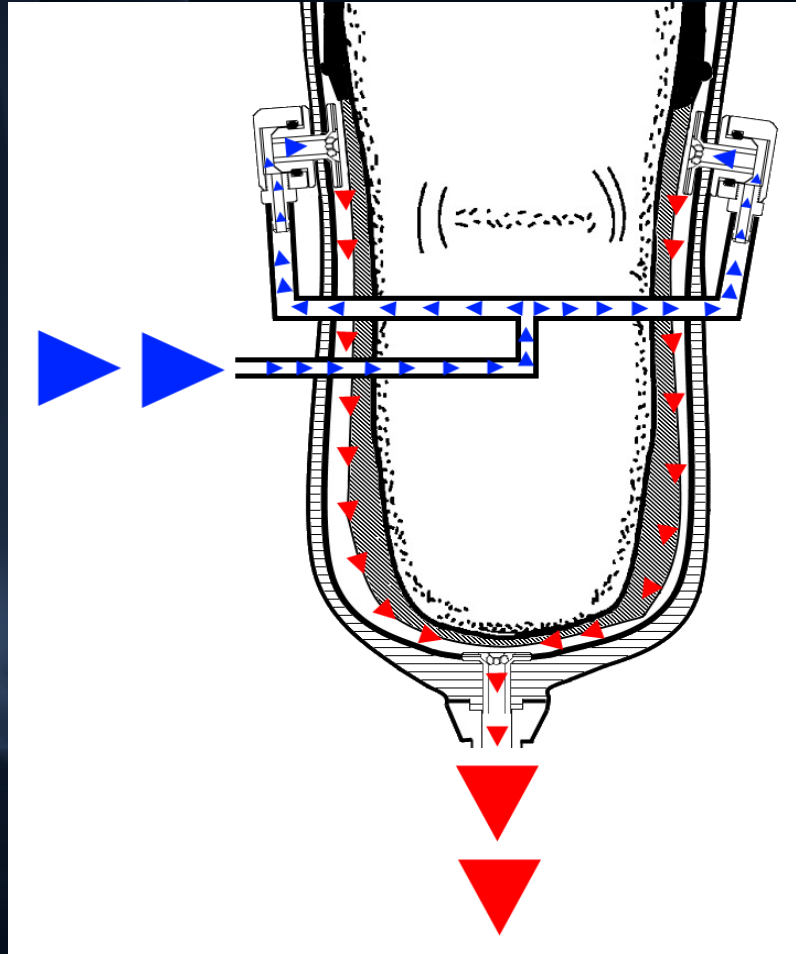
Objectives

- Maintain thermal comfort ($\sim 32^{\circ}\text{C}$)
- Prevent or expel perspiration to maintain adherence



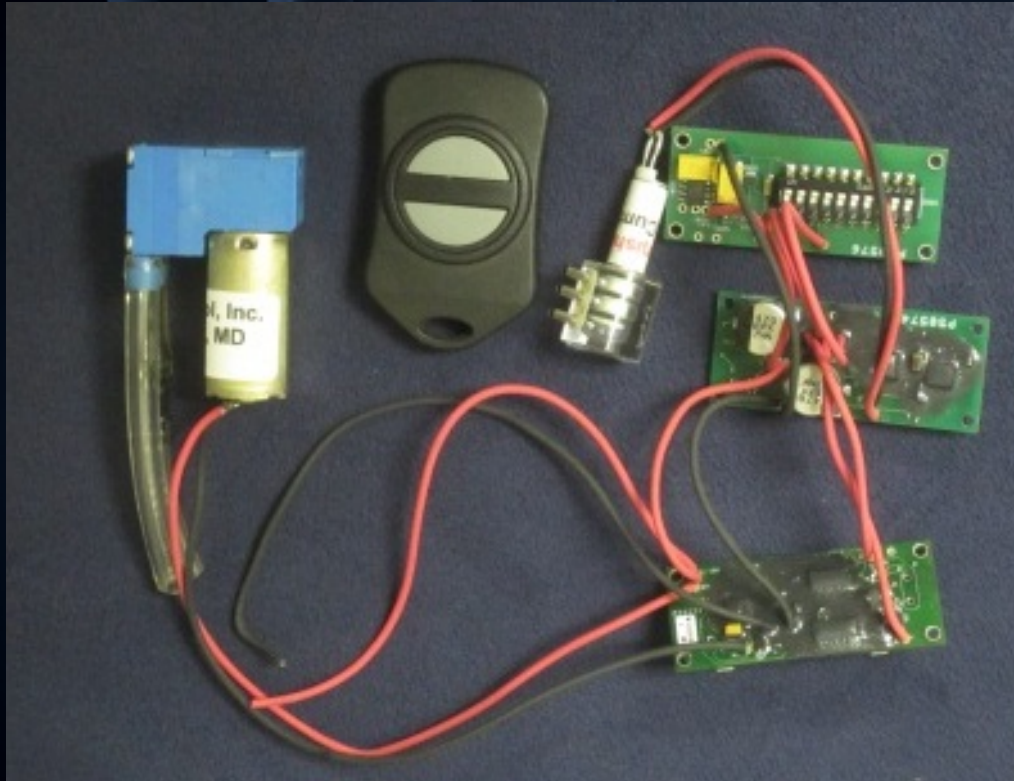
Methods: Socket & Suspension

Solenoid:
air in

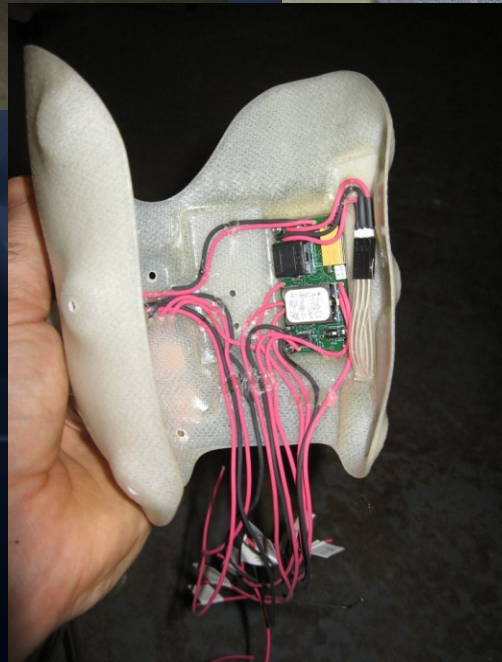


Pump: air and perspiration out while
maintaining suspension

Methods: Socket & Suspension



Methods: Socket & Suspension



Methods: Socket & Suspension



Methods: Participants

- Three transtibial amputees provided informed consent to participate in this IRB-approved protocol
 - 37 ± 12 yo
 - 5 ± 4 years post-amputation
 - 88 ± 24 kg and 1.8 ± 0.1 m
 - n=2 trauma, n=1 secondary to infection

Methods: Protocol

- Fit with study prostheses
 - TSB Suction
 - Dynamic Air Exchange (modified PTB Pin)
- Randomized order
- One week acclimation

Methods: Protocol

- Laboratory visit
 - Questionnaire
 - StepWatch Activity Monitor
 - Motion capture markers (limb pistoning)
 - Don Polartec hat and long sleeve shirt

Seated Rest 30 min

Treadmill 30 min

Seated Rest 30 min

Methods: Metrics

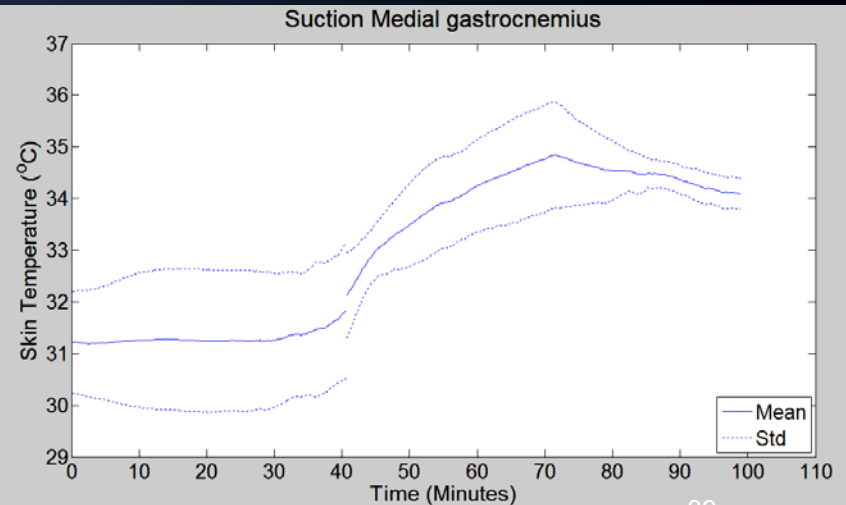
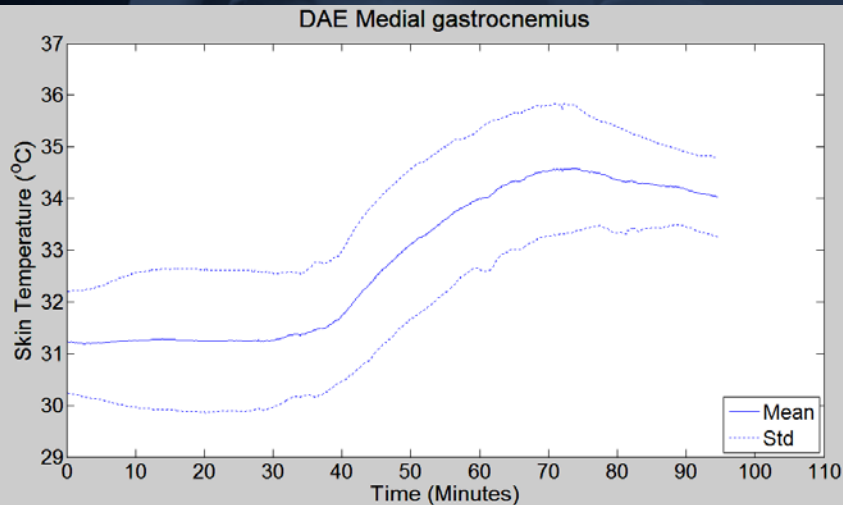
- Laboratory visit
 - Skin temperature (lat & med gastroc)
 - Sweat accumulation (tare weight)



Results

- Medial Gastroc Skin Temperature (n=3)

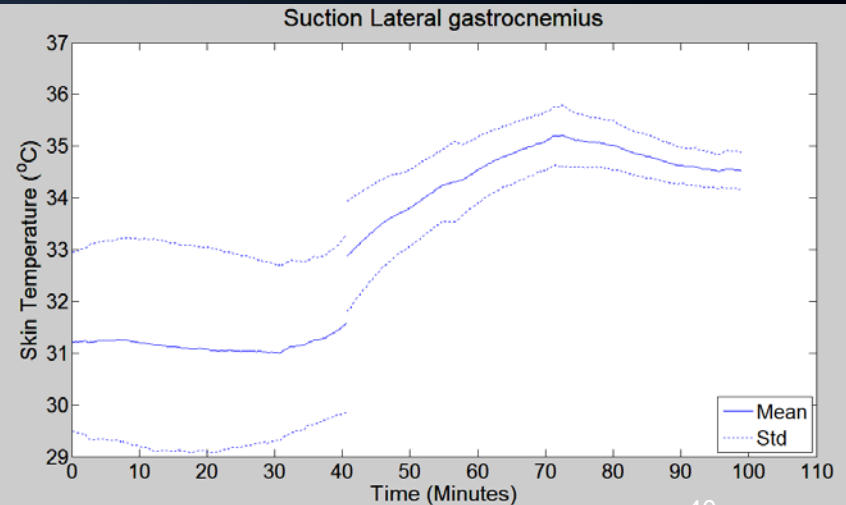
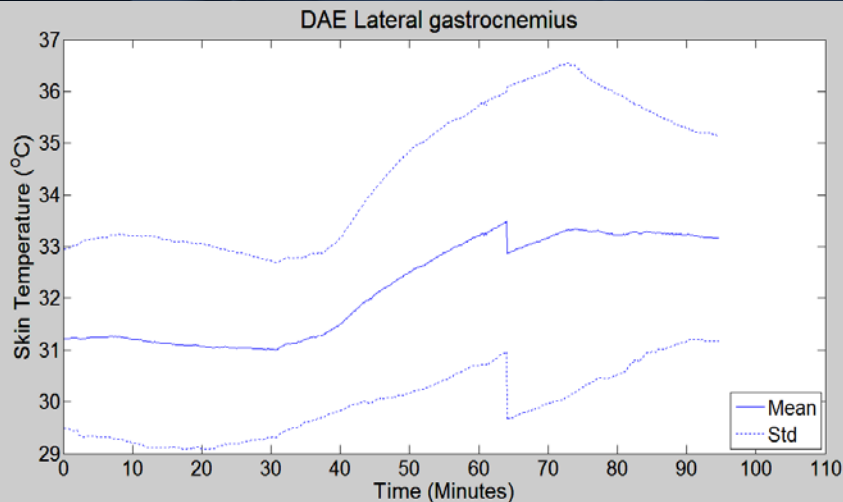
| | DAE | Suction |
|--------------------|----------------|----------------|
| Treadmill (30 min) | $+3.4 \pm 0.6$ | $+3.4 \pm 0.9$ |
| 2nd rest (30 min) | -1.0 ± 0.1 | -1.1 ± 0.5 |



Results

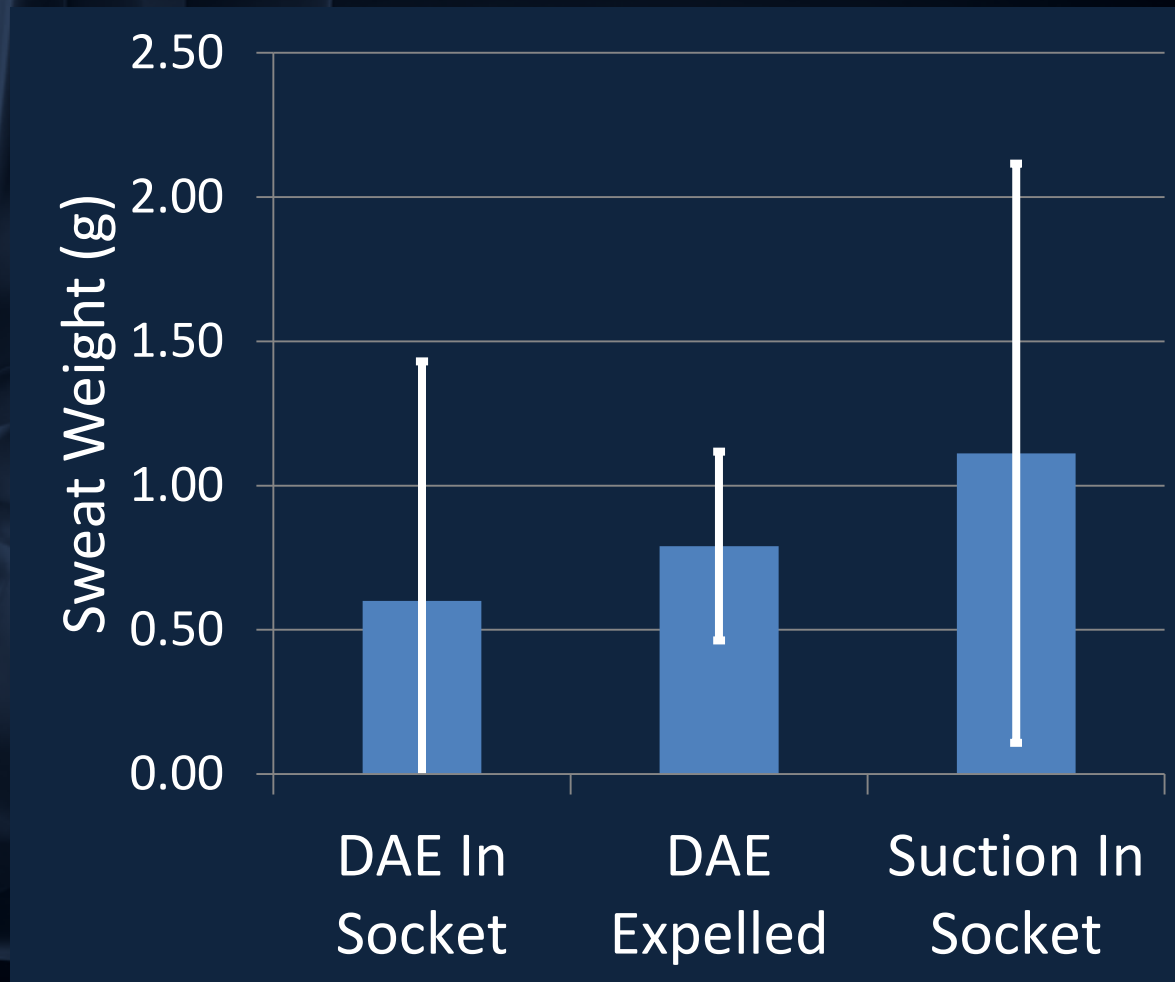
- Lateral Gastroc Skin Temperature (n=3)

| | DAE | Suction |
|--------------------|----------------|----------------|
| Treadmill (30 min) | $+2.9 \pm 0.3$ | $+2.7 \pm 0.9$ |
| 2nd rest (30 min) | -0.9 ± 0.7 | -0.8 ± 0.3 |



Results

- Sweat (n=3)



Discussion

- Cooling effects appear negligible
- Definitely expelling sweat
 - 1 g sweat clinically relevant (?)
- Initial protocol n=6



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This research was funded by the Department of the Army,
Advanced Prosthetics and Human Performance, US
Army Medical Research & Materiel Command at the
Telemedicine and Advanced Technology Research
Center (Grant: W81XWH-11-2-0169)